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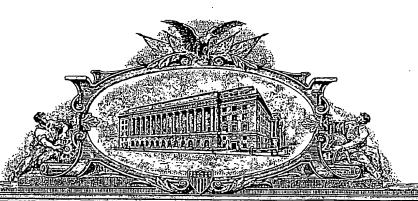
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APPLICATION NUMBER: 60/638,623 FILING DATE: December 22, 2004

By Authority of the

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P. R. GRANT Certifying Officer

# PROVISIONAL APPLICATION FOR PATENT COVER SHEET This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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## **EXPRESS MAIL CERTIFICATE**

DOCKET NO. :

28091/150 (13636US1-MLE)

APPLICANTS

JAMES HERMES KAAL, CRAIG STEPHEN THORLEY, AND

DAMIEN JUDD

TITLE

RETRACTABLE SYRINGE WITH PLUNGER DISABLING

**SYSTEM** 

Certificate is attached to the Provisional Patent Application which includes Specification and Claims (11 pages) of the above-named application.

"EXPRESS MAIL" NUMBER:

EV415647199US

DATE OF DEPOSIT:

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(Signature of person mailing paper or fee)

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# **EXPRESS MAIL CERTIFICATE**

DOCKET NO.

28091/150 (13636US1-MLE)

APPLICANTS :

JAMES HERMES KAAL, CRAIG STEPHEN THORLEY, AND

DAMIEN JUDD

TITLE

RETRACTABLE SYRINGE WITH PLUNGER DISABLING

**SYSTEM** 

Certificate is attached to the Provisional Patent Application Transmittal Letter (1 page) in duplicate and Fee Transmittal Letter (1 page) in duplicate of the above-named application.

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#### **EXPRESS MAIL CERTIFICATE**

DOCKET NO.

28091/150 (13636US1-MLE)

APPLICANTS

JAMES HERMES KAAL, CRAIG STEPHEN THORLEY, AND

DAMIEN JUDD

TITLE

RETRACTABLE SYRINGE WITH PLUNGER DISABLING

SYSTEM

Certificate is attached to the Drawings (10 pages) of the above-named application.

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TITLE:

RETRACTABLE SYRINGE WITH PLUNGER

**DISABLING SYSTEM** 

**INVENTORS:** 

JAMES HERMES KAAL, CRAIG STEPHEN

THORLEY, AND DAMIEN JUDD

DOCKET NO.:

28091/150

PROVISIONAL PATENT APPLICATION

R808834.1

# RETRACTABLE SYRINGE WITH PLUNGER DISABLING SYSTEM

#### FIELD OF THE INVENTION

[0001] This invention relates to syringes and plungers therefore. More particularly, this invention relates to permanently retractable syringes where the plunger can be automatically disabled.

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# BACKGROUND OF THE INVENTION

[0002] The practice of sharing syringes without adequate sterilization between successive users is a major contributor to the transfer of Human Immunodeficiency Virus and Hepatitis with subsequent severe repercussions for the sufferer of such diseases and at a high cost to society of supporting and providing medical attention to those sufferers.

[0003] Another significant risk associated with unclean needles and syringes arises from the possibility of inadvertent needle-stick injuries. This is particularly a problem for law enforcement officers and paramedics who often encounter users of illegal drugs in their professional activities. Additionally, the habits of illegal drug users are such that dangerous by-products of their activities, such as discarded syringes, are often left in places of public access presenting a risk to the users of areas such as public parks and school grounds.

[0004] Used syringes are also dangerous in hospitals, medical centers and surgeries where needlestick injuries may injure doctors, nurses and other health professionals.

[0005] A recent development in syringes has been to design syringes where the needle is permanently retractable into the barrel of the syringe.

[0006] For example, International Publication WO 01/80930 describes a single-use retractable syringe that is highly effective in preventing syringe re-use by ensuring full depression of the plunger during fluid delivery and by ensuring permanent withdrawal of the needle by the plunger back into the syringe barrel.

[0007] In such cases, retraction is facilitated by a spring located on the plunger and external to the syringe barrel. Depression of the plunger during injection compresses the spring against the barrel collar and engages the retractable needle with the plunger end, release of the plunger at the end of injection forces the plunger and needle engaged therewith to retract into the barrel automatically.

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[0008] Although very effective, prior art retractable syringes having spring-driven retraction mechanisms have limitations. One such limitation is that during delivery of the syringe contents, operating the plunger to compress a spring gives an undesirable feel to a user, which can provide a disincentive to use retractable syringes. Another such limitation is that for higher volume syringes, such as 3, 5 and 10 mL syringes, the size of the spring needed to drive retraction of the plunger and needle can be too large to fit into the syringe.

# SUMMARY OF THE INVENTION

15 [0009] The present invention is therefore broadly directed to a retractable syringe which comprises a mechanism to automatically disable the retractable syringe and thereby prevent re-use of the retractable syringe, wherein the mechanism comprises a compressed spring retained in association with a plunger, decompression of which spring forces retraction of a plunger member having a retractable needle engaged therewith.

[0010] An advantage of the syringe of the invention is that the spring is retained in a compressed state without the user having to compress the spring during plunger depression. This provides a smoother "feel" to the user during delivery.

25 [0011] In a first aspect or embodiment, the invention provides a plunger for a retractable syringe, the plunger comprising a first plunger member engageable with a second plunger member to co-operatively maintain a spring in an initial compressed state, the first plunger member capable of engaging a needle mount, in use disengagement of the first plunger member and the second plunger member

facilitating decompression of the spring which forces retraction of the first plunger member and the needle mount.

[0012] In another aspect, the invention provides a retractable syringe comprising the plunger of the first aspect.

In yet another aspect, the invention provides a retractable syringe comprising the retractable syringe of the second aspect and a needle mounted to the needle mount.

[0014] In an embodiment of the present invention, the first plunger member is engageable with the needle mount at the end of plunger depression, whereby decompression of the spring forces retraction of the first plunger member, the needle mount and the retractable needle when mounted thereto.

[0015] In other embodiments, the syringe further comprises a collar that includes one or more projections engageable with the plunger. The one or more projections of the collar and the first plunger member are co-operable to form a plunger disabling device that is capable of preventing subsequent depression and/or withdrawal of the first plunger member following retraction of the needle mount and needle.

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[0016] In other embodiments, the syringe is arranged so that following retraction of the needle mount and needle, subsequent coupling of a needle mount and/or needle to the syringe is disabled to thereby prevent syringe re-use.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Non-limiting embodiments of the invention are described herein with reference to the accompanying drawings in which:

[0018] FIG. 1 is a side view of an embodiment of a retractable syringe;

25 [0019] FIG. 2 is a perspective view of an embodiment of a first plunger member, a second plunger member with a seal and a spring with inset showing coupling device of first plunger member and second plunger member;

[0020] FIG. 3 is a perspective view of an embodiment of a barrel;

[0021] FIG. 4 is a perspective view of an embodiment of a barrel insert, an O-ring and a needle mount;

[0022] FIG. 5 is a perspective view of an embodiment of a collar;

5 [0023] FIG. 6 is a perspective view showing (A) the interaction of a collar projection and a slot in a first plunger member during plunger withdrawal; and (B) movement of the projection from the slot following plunger depression;

[0024] FIG. 7A and 7B are sequential perspective views showing engagement between a plunger rod and a needle mount;

10 [0025] FIG. 8 is a sectional view of a first plunger member just prior to disengaging a barrel insert from a needle mount;

[0026] FIG. 9 is a sectional view of a first plunger member having disengaged a barrel insert from a needle mount; and

[0027] FIG. 10 is a perspective view of an embodiment of a syringe disabling device.

# **DETAILED DESCRIPTION**

[0028] Referring to an embodiment shown in FIG. 1, retractable syringe 10 comprises barrel 20, plunger 30 and needle mount 40 with retractable needle 12. Needle mount 40 is mounted at needle end 23 of barrel 20 with barrel insert 50 and O-ring 55. Finger grips 25A, 25B are provided at plunger end 24 of barrel 20, at which end is mounted collar 60. Plunger 30 comprises first plunger member 31 with button 32 operable by a user and second plunger member 33 and seal 34 mounted thereto, coupled to first plunger member 31 to co-operatively maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12.

25 [0029] Referring now to FIG 2, plunger 30 comprises first plunger member in the form of plunger rod 31 having button 32 operable by a user, and second plunger member in the form of seal mount 33. When assembled, seal 34 is

mounted to seat 35 in seal mount 33, which in use, prevents or minimizes leakage of fluid between plunger 30 and internal wall 21 of barrel 20.

[0030] As specifically shown in the inset to FIG. 2, seal mount 33 is mounted to plunger rod 31 by a coupling device 300, which in this embodiment is a bayonet coupling formed between tabs 37A, 37B in seal mount 33 and respective coupling indents 38A, 38B in plunger rod 31. Coupling indents 38A, 38B are configured to allow restricted longitudinal movement (no more than about 1-2 mm) of seal mount 33 relative to plunger rod 31 when mounted thereto.

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[0031] Plunger rod 31 has a plurality of elongate, parallel vanes 310A,
 310B, 310C, 310D and 310E extending longitudinally along plunger rod 31.
 Vanes 310A, 310B define slot 311 having gate 312. Vanes 310B and 310C define retraction space 313.

[0032] Plunger rod 31 has reduced diameter portion 320 over which spring 70 is loaded, spring 70 bearing against rims 330A, 330B which thus cooperate with seal mount 33 when coupled to plunger rod 31 to maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12 is required. Spring 70 is shown non-compressed in FIG. 2.

[0033] Plunger rod 31 further comprises device 340 for engaging needle mount 40. In this embodiment, device 340 comprises opposed barbed arms 341A, 341B having barb ends 342A, 342B that can engage needle mount 40 at the end of plunger 30 depression, as will be described in more detail hereinafter.

[0034] Plunger rod further comprises steps 350A, 350B (not shown) which, together with ledges 351A, 351B, form part of disabling device 80 to be described in more detail hereinafter.

25 [0035] Referring to FIG. 3, barrel 20 is adapted so that needle mount 40 and barrel insert 50 can be fitted at needle end 23, while collar 60 can be mounted at plunger end 24. Tapered tabs 28A, 28B (not shown) facilitate mounting and retention of needle mount 40. Barrel 20 also comprises locating slots 29A, 29B at

plunger end 24 that facilitate mounting and retention of collar 60 and, at needle end 23, seat 210 for mounting O-ring 55.

[0036] With reference to FIG. 3 and FIG. 4, barrel insert 50 has annular body 51 with base 52 and arms 53A, 53B having respective grips 56A, 56B with angled faces 57A, 57B. O-ring 55 is fitted into seat 210 of barrel 20 to effect a seal between needle mount body 41 and internal wall 21 of barrel 20.

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[0037] Needle mount 40 comprises body 41 having central bore 42, base rim 43 and plunger-engaging portions 44A, 44B (not visible in FIG. 4) that comprise respective barb recesses 45A, 45B, angled faces 46A, 46B, lips 47A, 47B and upper ledges 48A, 48B. Needle mount body 41 further comprises opposed, tapered recesses 49A, 49B that in use are engaged by respective, tapered tabs 28A, 28B on inside wall 21 of barrel 20 to thereby fix needle mount 40 in position at needle end 23 of barrel 20 and limit movement of needle mount 40 toward needle end 23.

15 [0038] When assembled into syringe 10, base rim 43 of needle mount 40 is held by grips 56A, 56B of respective arms 53A, 53B of barrel insert 50, which prevents unwanted movement of needle mount 40 in the direction of plunger end 24 of barrel 20. In embodiments of the present invention, arms 53A, 53B of barrel insert 50 are oriented at approximately 90° relative to respective plunger-engaging portions 44A, 44B of needle mount 40, although other configurations can be used.

[0039] Arms 53A, 53B are resiliently deformable in the direction indicated by solid arrows. Radial outward movement of arms 53A, 53B allows release of needle mount 40 for subsequent retraction of needle mount 40 as will be described in more detail hereinafter.

25 [0040] An advantage provided by needle mount 40 is that a user may replace the needle should it become bent or burred, or should the needle gauge be changed (i.e between filling and delivery) without affecting the retraction mechanism.

[0041] A feature of needle mount 40 is that it may include whichever type of needle fitting is desired, such as luer taper 400, although without limitation thereto.

[0042] Referring to FIG. 3 and FIG. 5, barrel 20 comprises locating slots 29A, 29B (slot 29A not visible) in plunger end 24, which facilitate mounting of collar 60. Collar 60 has body 61 with a plurality of projections in the form of pawls 62A, 62B and ribs 63A, 63B and barrel-engaging shoulders 65A, 65B (shoulder 65B not visible) that fit into respective locating slots 29A, 29B (not shown) of barrel 20 to thereby mount collar 60 into plunger end 24 of barrel 20.

10 [0043] The operation of an assembled syringe 10 will now be described.

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[0044] As shown in FIG. 2, plunger 30 is assembled so that first plunger member 31 and second plunger member 33 are coupled by way of coupling device 300 to thereby maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12 fitted thereto, is required.

15 [0045] Referring to FIG. 6A, during withdrawal of plunger 30 to fill barrel 20 with fluid, rib 63A of collar 60 is slidably located in slot 311 of plunger rod 31 and rib 63B of collar bears against vane 310D (not visible in FIG. 6). This arrangement prevents rotation of plunger relative to collar 60 and needle mount 40 and maintains alignment of plunger device 340 for engaging needle mount 40 and plunger-engaging portions 44A, 44B of needle mount 40, at approximately 90° relative to respective arms 53A, 53B of barrel insert 50.

[0046] Withdrawal of plunger 30 is limited by abutment 360 in slot 311 bearing against rib 63A of collar 60. The particular position of abutment 360 in slot 311 will therefore determine the length of travel of plunger 30 and hence the volume of fluid that is drawn into barrel 20. For example, FIG. 2 shows the location of abutment 360 for a 3 mL syringe; for a 5 mL syringe ledge 351A acts as abutment 360.

[0047] At the end of plunger 30 withdrawal, the fluid contents of syringe 10 are delivered by depression of plunger 30.

[0048] At the end of delivery, there are three events that occur.

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[0049] Firstly, needle mount 40 is disengaged from barrel insert 50 to allow retraction of needle mount 40 and needle 12.

[0050] Secondly, plunger rod 31 engages needle mount 40 via engaging device 340 to retract needle mount 40 and needle 12.

[0051] Thirdly, plunger rod 31 and seal member 33 are disengaged to allow decompression of spring 70, which drives retraction of plunger rod 31, needle mount 40 and needle 12 coupled therewith.

[0052] At the end of delivery, in order to release needle mount 40 from
barrel 20, plunger lip 366 of plunger 30 forcibly displaces respective arms 53A,
53B of barrel insert 50 radially outwardly in the direction shown in FIG. 3, to thereby disengage grips 56A, 56B from base rim 43 of needle mount 40. This is accompanied by barbs 342A, 342B of plunger rod 31 engaging ledges 47A, 47B in needle mount 40 to thereby facilitate retraction of needle mount 40 by plunger
30, as shown in FIG. 7A and FIG. 7B.

spreads arms 53A, 53B of barrel insert 50 radially outwardly as indicated by the solid arrows. Angled faces 57A, 57B of arms 53A, 53B slide against plunger lip 366, causing barrel insert 50 to slide towards O-ring 55 after grips 56A, 56B of arms 53A, 53B have cleared base rim 43 of needle mount 40. As best seen in FIG. 9, respective corners 58A, 58B of arms 53A, 53B come to rest on the outside of needle mount body 41 to permanently release the needle mount 40 and allow it to pass through barrel insert 50 and seal mount 33 which are retained at needle end 23 of barrel 20 by spring 70. At this location, barrel insert 50 can no longer retain a needle mount 40, thereby permanently disabling syringe 10 by preventing refitting of a needle mount 40.

[0054] As best seen in FIG. 7A, during engagement of respective plunger engaging device 44A, 44B in seal mount 40 by barbs 342A, 342B of plunger rod 31, inclined edges 343A, 343B of barbed arms 341A, 341B of plunger rod 31 bear

against respective, complementary angled faces 46A, 46B on needle mount 40 which forces a slight rotation of plunger rod 31 relative to seal member 33 in the direction indicated by the arrow in FIG. 7A, which facilitates disengagement of bayonet coupling 300.

- Disengagement of plunger rod 31 and seal mount 33 allows decompression of spring 70 which pushes against seal mount 33 and rim 330 on plunger rod 31 to thereby force retraction of plunger rod 31 together with needle mount 40 and needle 12 engaged therewith. Seal mount 33 and barrel insert 50 remain at needle end 23 of barrel 20.
- 10 [0056] Disengagement of plunger rod 31 from seal mount 33 allows decompression of spring 70 and retraction of plunger rod 31 with needle mount 40 and needle 12 attached thereto, followed by activation of disabling device 80 to prevent subsequent movement of plunger rod 31. When plunger rod 31 rotates just prior to retraction, rib 63A of collar 60 slidably moves through gate 312 from slot 311 into retraction space 313, as shown in FIG. 6B, which thereby allows plunger rod 31 to retract while aligning pawls 62A, 62B of collar 60 with steps 350A, 350B of plunger rod 31.
- [0057] Steps 350A, 350B are configured to allow travel of pawls 62A, 62B thereover as plunger rod 31 retracts, but to resist subsequent depression of plunger rod 31, by pawls 62A, 62B (not shown) bearing against steps 350A, 350B (not shown) once disabling device 80 has been activated, as shown in FIG. 10.
  - [0058] Also evident in FIG. 10 is that disabling device 80 prevents further withdrawal of plunger rod 31 by ribs 63A, 63B of collar 60 bearing against ledges 351A, 351B of plunger rod 31.
- 25 [0059] It should also be noted that following retraction of plunger rod 31 and needle mount 40, barrel insert 50, O-ring 55, seal mount 33 and seal 34 remain at needle end 23 of barrel 20 (not shown), thereby preventing refilling of barrel 20 from needle end 23.

[0060] It will be understood in light if the foregoing that the invention provides a robust, simple to operate automatically-disabling syringe that prevents subsequent reuse and thereby minimizes the potential for disease transfer while also reducing the likelihood of needlestick injuries to the user.

- Having thus described the basic concept of the invention, it will be rather apparent to those skilled in the art that the foregoing detailed disclosure is intended to be presented by way of example only, and is not limiting. Various alterations, improvements, and modifications will occur and are intended to those skilled in the art, though not expressly stated herein. These alterations, improvements, and modifications are intended to be suggested hereby, and are within the spirit and scope of the invention. Additionally, the recited order of processing elements or sequences, or the use of numbers, letters, or other designations therefore, is not intended to limit the claimed processes to any order except as may be specified in the claims. Accordingly, the invention is limited

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only by the following claims and equivalents thereto.

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# **CLAIMS**

What is claimed is:

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and

A plunger for a retractable syringe, the plunger comprising:
 a first plunger member;

a second plunger member; and

a spring, wherein the first plunger member is engageable with the second plunger member to co-operatively maintain the spring in an initial compressed state, the first plunger member capable of engaging a needle mount; and

wherein disengagement of the first plunger member and the second plunger member facilitates decompression of the spring which forces retraction of the first plunger member and the needle mount.

2. A retractable syringe, the syringe comprising:

a needle mount for a needle;

a plunger comprising first and second plunger members; and

a spring, wherein the first plunger member is engageable

with the second plunger member to co-operatively maintain the spring in an initial

compressed state, the first plunger member capable of engaging a needle mount;

wherein disengagement of the first plunger member and the second plunger member facilitates decompression of the spring which forces retraction of the first plunger member and the needle mount.

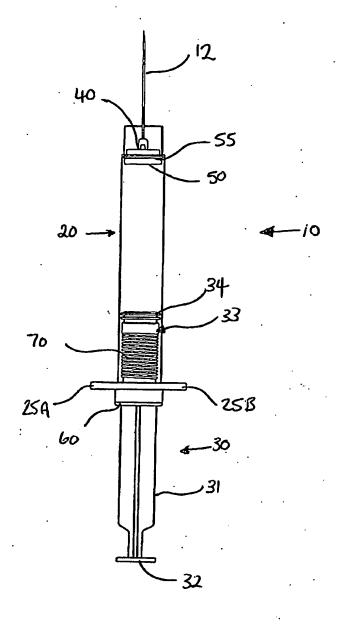
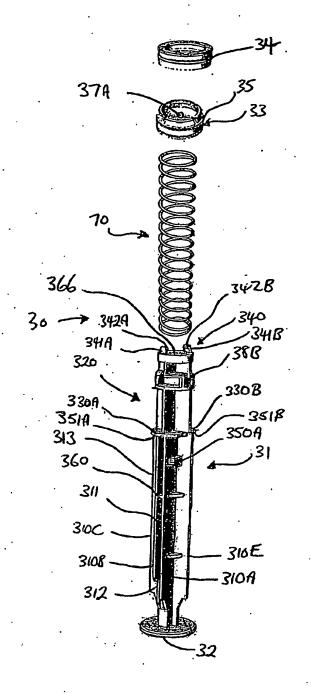


FIG. 1



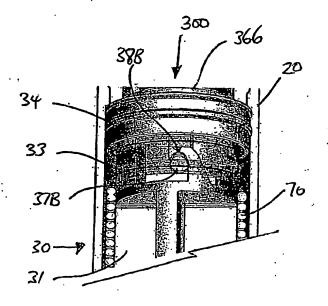
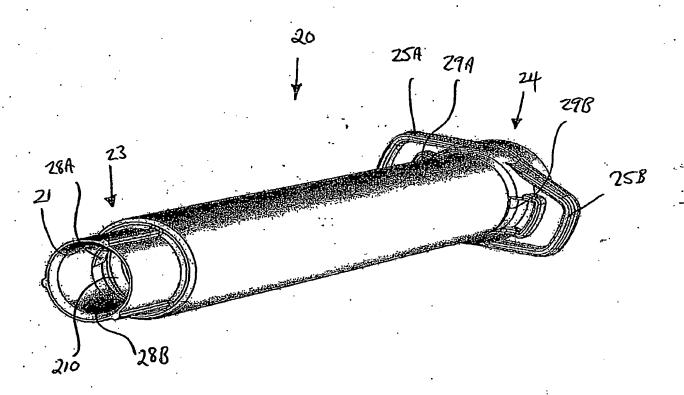
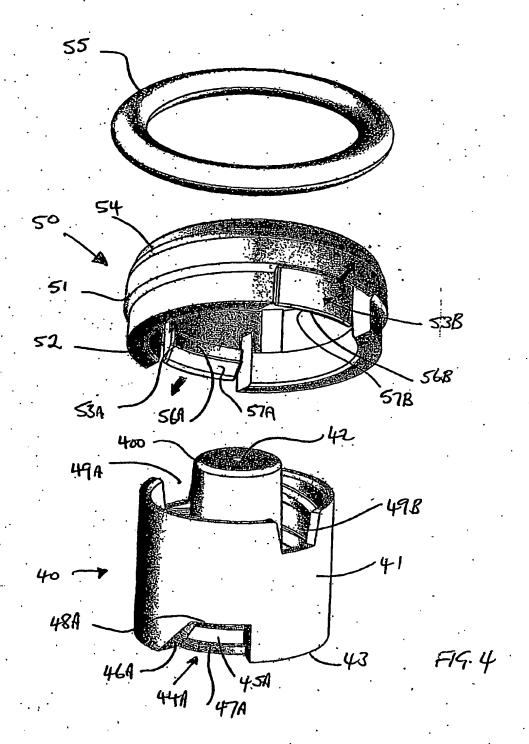
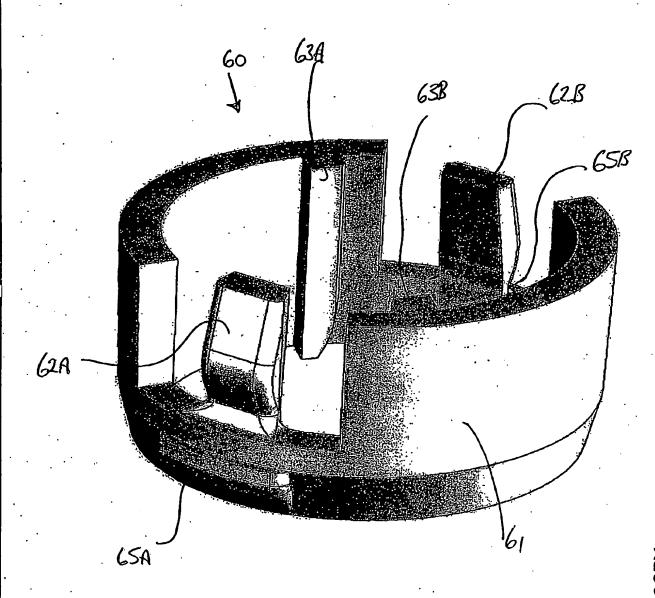


FIG. 2

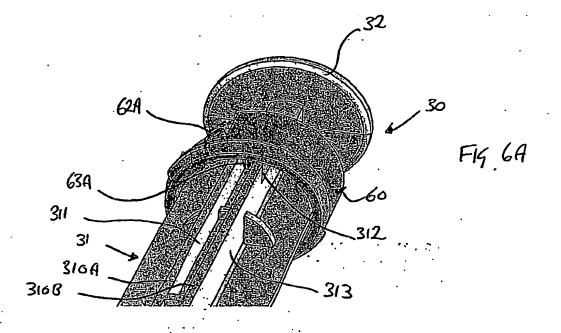


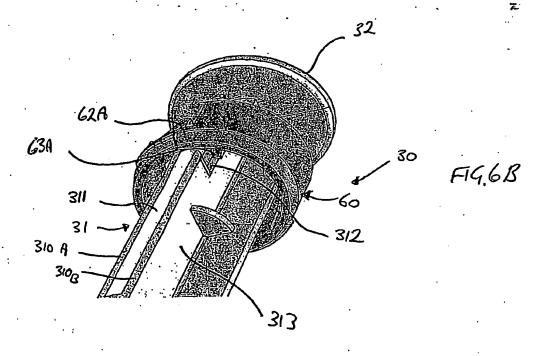
F14. 3





F19.5





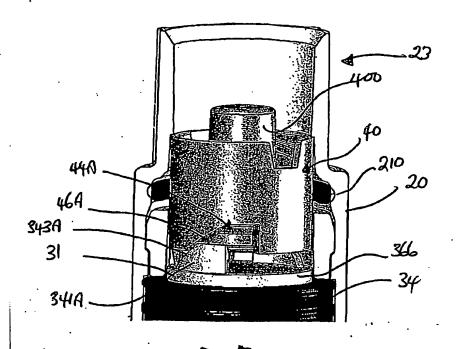
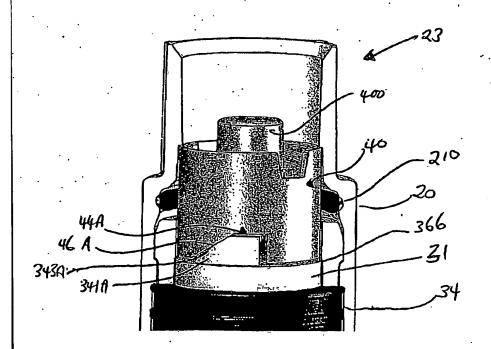
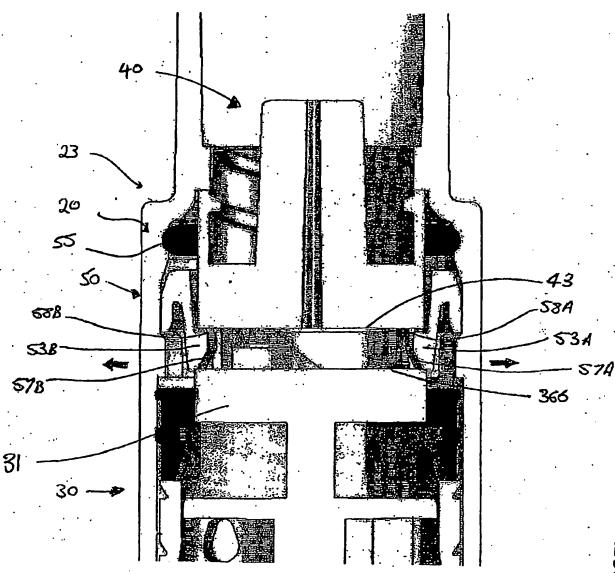


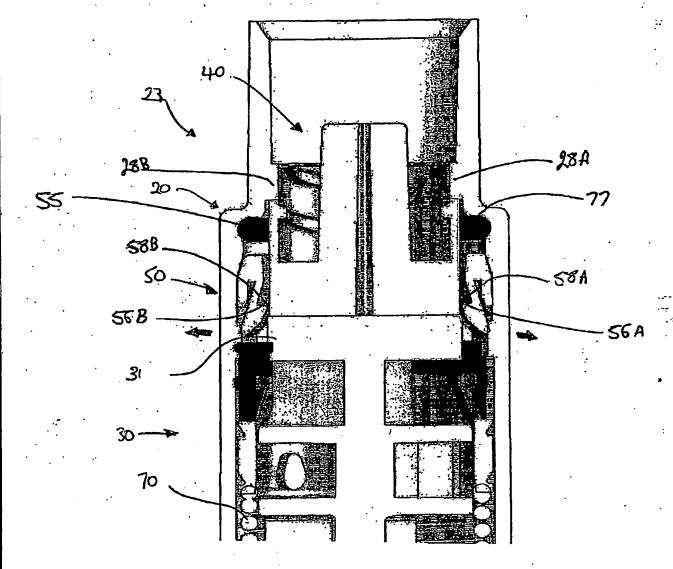
FIG 7A



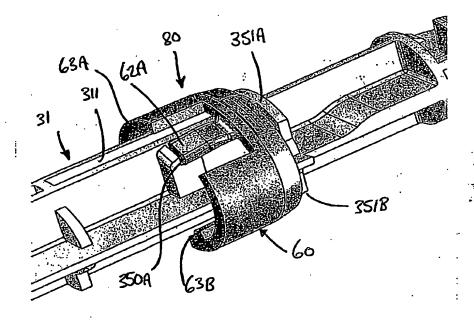
F147B



F19-8



Fiq. 9



F19.10

#### From the INTERNATIONAL BUREAU

# **PCT**

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT To

FISHER ADAMS KELLY Level 13 AMP Place . 10 Fagle Street Brisbane, Queensland 4000 AUSTRALIE

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year)

11 July 2005 (11.07.2005)

Applicant's or agent's file reference
12897PC2-MLE

International application No.
PCT/AU2005/000107

International publication date (day/month/year)

International publication date (day/month/year)

Priority date (day/month/year)
28 January 2004 (28.01.2004)

Applicant

UNITRACT SYRINGE PTY LTD et al

- 1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- 2. (If applicable) The letters "NR" appearing in the right-hand column denote a priority document which, an the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- 3. (If applicable) An asterisk (\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office	
		or PCT receiving Office	of priority document
28 January 2004 (28.01.2004)	2004900362	ΑU	15 March 2005 (15.03.2005)
22 October 2004 (22.10.2004)	2004906116	AU	15 March 2005 (15.03.2005)
22 December 2004 (22.12.2004)	60/638,623	US	08 July 2005 (08.07.2005)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

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CIEW7KIL

#### From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To

FISHER ADAMS KELLY Level 13 AMP Place 10 Eagle Street Brisbane, Queensland 4000 AUSTRALIE

Date of mailing (day/month/year) 18 March 2005 (18.03.2005)	
Applicant's or agent's file reference 12897PC2-MLE	IMPORTANT NOTIFICATION
International application No. PCT/AU05/000107	International filing date (day/month/year) 28 January 2005 (28.01.2005)
International publication date (day/month/year)	Priority date (day/month/year) 28 January 2004 (28.01.2004)
Applicant UNITRA	CT SYRINGE PTY LTD et al

- 1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
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Form PCT/IB/304 (January 2004)